

# ISO 11197:2016-02 (E)

## Medical supply units

---

### Contents

Foreword ..... v

Introduction..... viii

201.1 Scope,object and related standards ..... 1

201.1.1 Scope..... 1

201.1.2 Object..... 1

201.1.3 Related standards..... 1

201.1.3.1 Collateral standards..... 1

201.1.3.2 Particular standards ..... 2

201.2 Normative references ..... 2

201.3 Terms and definitions ..... 4

201.4 General requirements ..... 5

201.5 General requirements for testing ME EQUIPMENT ..... 5

201.6 Classification of ME EQUIPMENT and ME SYSTEMS ..... 5

201.7 ME EQUIPMENT identification, marking and documents ..... 5

201.8 Protection against electrical HAZARDS from ME EQUIPMENT ..... 9

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS..... 15

201.10 Protection against unwanted and excessive radiation HAZARDS ..... 17

201.11 Protection against excessive temperatures and other HAZARDS ..... 17

201.12 Accuracy of controls and instruments and protection against hazardous outputs ..... 17

201.13 HAZARDOUS SITUATIONS and fault conditions ..... 17

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ..... 18

201.15 Construction of ME EQUIPMENT ..... 18

201.16 ME SYSTEMS ..... 23

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS..... 23

202 MEDICAL ELECTRICAL EQUIPMENT - part 1-2 General requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE – Collateral standard: Electromagnetic disturbances – Requirements and tests ..... 23

206 MEDICAL ELECTRICAL EQUIPMENT - part 1-6 General requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE – Collateral standard: Usability..... 23

Annex AA (informative) Rationale .....24

Bibliography ..... 25